

§ 892.1

- 892.1830 Radiologic patient cradle.
- 892.1840 Radiographic film.
- 892.1850 Radiographic film cassette.
- 892.1860 Radiographic film/cassette changer.
- 892.1870 Radiographic film/cassette changer programmer.
- 892.1880 Wall-mounted radiographic cassette holder.
- 892.1890 Radiographic film illuminator.
- 892.1900 Automatic radiographic film processor.
- 892.1910 Radiographic grid.
- 892.1920 Radiographic head holder.
- 892.1940 Radiologic quality assurance instrument.
- 892.1950 Radiographic anthropomorphic phantom.
- 892.1960 Radiographic intensifying screen.
- 892.1970 Radiographic ECG/respirator synchronizer.
- 892.1980 Radiologic table.
- 892.1990 Transilluminator for breast evaluation.
- 892.2010 Medical image storage device.
- 892.2020 Medical image communications device.
- 892.2030 Medical image digitizer.
- 892.2040 Medical image hardcopy device.
- 892.2050 Picture archiving and communications system.

Subparts C–E [Reserved]

Subpart F—Therapeutic Devices

- 892.5050 Medical charged-particle radiation therapy system.
- 892.5300 Medical neutron radiation therapy system.
- 892.5650 Manual radionuclide applicator system.
- 892.5700 Remote controlled radionuclide applicator system.
- 892.5710 Radiation therapy beam-shaping block.
- 892.5730 Radionuclide brachytherapy source.
- 892.5740 Radionuclide teletherapy source.
- 892.5750 Radionuclide radiation therapy system.
- 892.5770 Powered radiation therapy patient support assembly.
- 892.5780 Light beam patient position indicator.
- 892.5840 Radiation therapy simulation system.
- 892.5900 X-ray radiation therapy system.
- 892.5930 Therapeutic x-ray tube housing assembly.

Subpart G—Miscellaneous Devices

- 892.6500 Personnel protective shield.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 53 FR 1567, Jan. 20, 1988, unless otherwise noted.

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Subpart A—General Provisions

§ 892.1 Scope.

(a) This part sets forth the classification of radiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a radiology device that has two or more types of uses (e.g., use both as a diagnostic device and a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of this title 21, unless otherwise noted.

§ 892.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during